

REMARKS

Claims 9-16 currently appear in this application. The Office Action of April 23, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Applicant's attorney wishes to thank Examiners Ragonese and Lewis for the courtesies extended during the interview of June 2, 2004. The present amendment is in response both to the Office Action of April 23 and the observations on newly cited U.S. Patents made during the interview of June 2, 2004 in response to the draft amendment submitted prior to the interview. This new art has been used in amending the claims.

Information Disclosure Statement

The Examiner stated that listing of the references in the specification is not a proper information disclosure statement.

Attention is directed to the Information Disclosure Statement filed September 11, 2003, which lists the patents cited on Form PTO/SB/08A. It is believed that the references listed in the specification have been properly cited.

Specification

The Abstract of the Disclosure is objected to because of the use of improper sentence structure.

Submitted herewith on a separate sheet of paper is a new Abstract of the Disclosure, correcting the typographical error that resulted in an incomplete sentence.

Art Rejections

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalhok et al.

This rejection is respectfully traversed. Claims 1-8 have now been replaced by new claims 9-16, which claims recite that the mask comprises a material for filtering air. Kalhok et al. disclose a helmet which includes a breathing mask which is connected to the face portion of a helmet through flexible tubes to link the breathing mask to the outside. The breathing mask comprises a mask body, surrounding the nose and mouth of the wearer and including a port on each side adjacent the mouth; a flexible tube which connects the port to the passage when the face portion is in the closed position, a binding member adapted to secure the breathing mask to the helmet, and resilient straps (page 5, penultimate paragraph). The invention also provides a filter for a breathing mask comprising a thin layer of material adapted to isolates [sic] the skin of a wearer from the breathing mask, the layer of

material shaped to fit a given contour of the breathing mask (page 6, penultimate paragraph).

It is clear that Kalhok et al. describe a helmet (10) rather than a mask comprising a filtering material. It is clear from the specification as filed, paragraph 0055, that the filtering portion of the mask can be made of any acceptable material which will filter airborne pathogens or dust.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalhok et al. in view of Sarazen.

This rejection is respectfully traversed. As noted above, the helmet of Kalhok et al. has little to do with the mask made of filtering material according to the present invention. Sarazen adds nothing to Kalhok et al. to arrive at the mask claimed in claim 5. Additionally, Sarazen discloses a welder's shield, not a mask made of a filtering material.

During the June 2 interview, Examiners Ragonese and Lewis noted that the following patents were also relevant to the present invention:

DeSaint Rapt et al., 2,023,267

Colley, 3,067,425

Rollins, III, et al., 4,328,797

Sarnoff et al., 4,433,684

Spector et al., 4,424,833

Vanderputte, 4,841,963

DeSaint Rapt et al. disclose a feeding means for gas masks comprising a series of membranes or discs of rubber forming a valve. A breathing tube is provided to fit through the valve to provide liquid or oxygen to the wearer. The mask of DeSaint Rapt et al. differs from the mask of the present invention in that the mask is completely sealed to protect the wearer from poisonous gases. The mask of the present invention, on the other hand, is made of filter media so that the wearer can comfortably breathe through the mask at all times. The mask of the present invention is designed to filter particulates and microorganisms to prevent infection or exposure to allergens. The opening of the mask is closed until the wearer chooses to introduce an object thereinto for taking nourishment or hydration.

Colley discloses a flying suit helmet with a penetrable sealing closure. As with DeSaint Rapt et al., Cooley provides a covering for the head which completely seals out the ambient atmosphere, having only a closure for permitting temporary insertion of a tube for enabling the wearer to receive food and liquid or to smoke, under high altitude flight conditions. Cooley provides a helmet which is internally pressurized to enable the wearer to breathe, which helmet is of necessity completely sealed except for the

opening for a tube. The helmet of Cooley is not made of filter media and does not filter particulates or microorganisms from the air the wearer breathes.

Rollins, III et al. disclose a mask for delivery of gas to a patient which can include an opening for a nasogastric intubation procedure. Since this mask is an oxygen mask, it is of necessity made of an impermeable material so that the patient's nose and mouth are surrounded by the oxygen introduced into the mask. There is no need for a filtering material, particularly since any filtering material would permit the oxygen to leave the area under the mask to the detriment of the patient.

Spector et al. disclose a self-sealing gasket assembly through which tubes may be inserted and removed and wherein the valve-like gasket maintains a seal at all times. Column 1, lines 1-46, describes the types of devices which can use such a valve, including gas masks or sealed helmets, a catheter introducer, and needles or similar tubular introducer devices. There is neither teaching nor suggestion of using this valve with a mask made of material such as a filtering media.

Sarnoff et al. disclose an assembly for enabling a respiratory medicament to be administered to a gas mask wearer without breaking the seal between the face of the gas mask and

the wearer's face. This device is designed to administer medicament to one whose mouth and nose are completely sealed off from the ambient air, rather than to one whose nose and mouth are covered by a mask comprising a filtering material. In the mask of the present invention, the wearer breathes ambient air that has been filtered; there is no sealing off the nose and mouth from the ambient air.

Vandeputte discloses a gas mask which is capable of connecting the inside with the outside environment. However, this is a gas mask, which means that the wearer's nose and mouth are effectively sealed off from the ambient air. This is totally unlike the mask of the present invention, in which the wearer breathes ambient air but the air the wearer breathes is filtered to remove particulates, microorganisms, and allergens.

All of the patents cited during the June 2 interview relate to openings that can be covered in gas masks or other devices that keep the wearer from breathing ambient air. The mask of the present invention, on the other hand, is designed so that the wearer breathes ambient air, but this air is filtered for the wearer. The openings in the masks in the cited patents are designed to introduce nourishment, etc. without admitting ambient air into the area under the mask. The present invention, on the other hand, is designed to

maintain the filtering material over the nose and mouth of the wearer, but the wearer breathes ambient air at all times. There is no suggestion in any of the cited patents that the self-closing openings or valves can be used with a device that does not completely seal out ambient air. Without some motivation to construct a mask made of filtering material using the openings disclosed in the cited patents, there can be no finding of obviousness.

As the Federal Circuit stated in *In re Lee*, 61 USPQ2d 1430 (January 18, 2002, Fed. Cir.), "As applied to the determination of patentability *vel non*, when the issue is obviousness, 'it is fundamental that rejections under 35 U.S.C. 103 must be based on evidence comprehended by the language of that section.' *In re Grasselli*, 53 USPQ2d 1769, 1774 (Fed. Cir. 2000)... When patentability turns on the question of obviousness, the search for an analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., *McGinley v. Franklin Sports, Inc*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ('the central question is whether there is a reason to combine [the] references,' a question of fact drawing on the *Graham* factors."

'The factual inquiry whether to combine references must be thorough and searching.' *Id.* This precedent has been reinforced in myriad decisions, and cannot be dispensed with, *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000). ('a showing of a suggestion, teaching, or motivation to combine the prior art references is an "essential component of an obviousness holding"'') (quoting *C. R. Bard, Inc. v. M3 Systems, Inc.* 48 USPQ2d (Fed. Cir. 1998)) The Court went on to quote *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."

There is a requirement for specificity in combining references, *See, In re Kotzab*, 55 USPQ2d 13134, 1317 (Fed. Cir. 2002) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.").

In the present case, the Examiner has shown no motivation to use the valve or openings disclosed in the cited references in a mask such as claimed herein.

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In view of the above, it is respectfully submitted
that the claims are now in condition for allowance, and
favorable action thereon is earnestly solicited.

Respectfully submitted,

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